Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 204

Report Date:04/29/2009

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	059902703 050517405 059900705 059201305 052000803	08/12/02 08/05/02 04/21/03 01/20/00 03/04/03	729 729 729 729 730 729	50 (3) 50 (3) 50 (3) 50 (3) 50 (3)	37(705) 33(703) 33(679) 31(702) 36(704)	452.8 510.0 460.9 448.0 452.1	Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract
				Fen	nale		
Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	059902703 050517405 059900705 059201305 052000803	08/12/02 N/A 04/21/03 01/20/00 03/04/03	733 N/A 731 735 732	50 (5) 0 (0) 50 (5) 50 (5) 50 (5)	36(702) 0(0) 30(699) 40(702) 38(693)	314.7 N/A 326.0 311.3 328.4	Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract

: May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 205

			Male				Female	
All Organs: Benign Tumors								
3		49/50 (98%) 50/50 (100%)	50/50 (100%) 50/50 (100%)	47/50 (94%)		45/50 (90%) 48/50 (96%)	39/50 (78%)	46/50 (92%)
verall Incidence	Total	246/250 (98.4%)	Mean 98.4%	SD 2.61%	Total	178/200 (89%)	Mean 89%	SD 7.75%
All Organs: Malignant Tumors							•••••	
		27/50 (54%) 22/50 (44%)	23/50 (46%) 26/50 (52%)	29/50 (58%)		15/50 (30%) 19/50 (38%)	18/50 (36%)	19/50 (38%)
Overall Incidence	Total	127/250 (50.8%)	Mean 50.8%	SD 5.76%	Total	71/200 (35.5%)	Mean 35.5%	SD 3.79%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%) 50/50 (100%)	50/50 (100%) 50/50 (100%)	50/50 (100%)		47/50 (94%) 48/50 (96%)	46/50 (92%)	48/50 (96%)
Overall Incidence	Total	250/250 (100%)	Mean 100%	SD 0%	Total	189/200 (94.5%)	Mean 94.5%	SD 1.91%
All Organs: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ontrol Animal Groups

Page: 206

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
All Organs: Hemangiosarcoma or He	emangioma					
•	J	2/50 (4%)	0/50 (0%) 0/50	0 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 3/250 (1.2%)	1/50 (2%) Mean 1.2% S	D 1.79% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
		` ,	Wican 1.270		, ,	
All Organs: Histiocytic Sarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 3/50 (6%)	0 (0%)	1/50 (2%) 2/50 (4%) 0/50 (0%)	1/50 (2%)
verall Incidence	Total	3/250 (1.2%)	` '	D 2.68% Total	2/50 (4%) 0/50 (0%) 4/200 (2%) Mean 2%	SD 1.63%
vo.u.i moidonos		0,200 (1.2,0)	Wodii 1.270		1,250 (270) Modif 270	05 1.0070
All Organs: Leukemia: Erythrocytic						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	0 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/50 (0%)	` '	D 0% Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%) Mean 0.5%	SD 1%
· oran moraonoo		0,200 (0,0)	Modifi 070		1/200 (0.070) Modifi 0.070	
All Organs: Leukemia: Lymphocytic Undifferentiated	, Monocytic, M	Iononuclear, or				
		19/50 (38%)	15/50 (30%) 21/5	50 (42%)	9/50 (18%)	9/50 (18%)
verall Incidence	Total	15/50 (30%) 87/250 (34.8%)	17/50 (34%) Mean 34.8% S	D 5.22% Total	9/50 (18%) 6/50 (12%) 33/200 (16.5%) Mean 16.5%	SD 3%
	Total	` ,			( 1 1 1 )	3D 3%
NI Organs: Malignant Lymphoma: H or Undifferentiated Cell	listiocytic, Lyn		,			
	71	0/50 (0%)	1/50 (2%) 0/50	0 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	<b>-</b>	0/50 (0%)	0/50 (0%)	D 0 000/	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	OD 00/
	Total	1/250 (0.4%)	Mean 0.4% S	D 0.89% Total	0/200 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 207

			Male				Female	
All Organs: Mesothelioma: Benign		0/50 (09/)	0/50 (00/)	0/50 (09/)		0/50 /00/		0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs:								
Mesothelioma: Benign, Mal	ilgnant, NOS	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs:  Mesothelioma: Malignant	•••••							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteoma	•••••				•••••			
Osteoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male Female #All Organs: Osteosarcoma or Osteoma 0/50 (0%)(0%)(4%)0/50 (0%)(0%)(0%)0/50 1/50 (2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/250 (1.2%) Mean 1.2% SD 1.79% Total 1/200 (0.5%) Mean 0.5% SD 1% \*Adrenal Cortex: Adenoma 0/50 (0%)0/50 (0%)2/50 (4%)1/50 (2%)1/50 (2%)(4%)(2%)**Overall Incidence** Total Mean 1.2% SD 1.79% Total 4/197 (2.03%) Mean 2.01% SD 1.63% 3/250 (1.2%) \*Adrenal Cortex: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/197 (0%) Mean 0% \*Adrenal Medulla: Ganglioneuroma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/48 (0%)(0%)**Overall Incidence** 0/249 (0%) SD 0% SD 0% Total Mean 0% Total 0/194 (0%) Mean 0% \*Adrenal Medulla: Hemangioma (0%)0/50 (0%)0/50 0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)0/48 (0%)**Overall Incidence** Total 0/249 (0%)Mean 0% SD 0% Total 0/194 (0%) Mean 0% SD 0%

Page: 208

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 209

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	enian							
	3	8/50 (16%) 8/50 (16%)	8/50 (16%) 5/50 (10%)	5/49 (10%)		1/50 (2%) 2/48 (4%)	1/48 (2%)	0/48 (0%)
verall Incidence	Total	34/249 (13.65%)	Mean 13.64%	SD 3.23%	Total	4/194 (2.06%)	Mean 2.06%	SD 1.7%
Adrenal Medulla: Pheochromocytoma Co			•••••					
•	•	0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	1/48 (2%)	0/48 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/194 (0.52%)	Mean 0.52%	SD 1.04%
Adrenal Medulla: Pheochromocytoma Ma	alignant							
		3/50 (6%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/49 (2%)		2/50 (4%) 1/48 (2%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	4/249 (1.61%)	Mean 1.61%	SD 2.61%	Total	3/194 (1.55%)	Mean 1.52%	SD 1.92%
Adrenal Medulla:		. Malianaut NOC			• • • • • • • • • • • • • • • • • • • •			
Pheochromocytoma: B	enign, Complex	11/50 (22%)	8/50 (16%)	6/49 (12%)		3/50 (6%)	0/40 (40/)	0/48 (0%)
Overall Incidence	Total	10/50 (20%) 41/249 (16.47%)	6/50 (12%) Mean 16.45%	SD 4.5%	Total	3/48 (6%) 8/194 (4.12%)	2/48 (4%) Mean 4.1%	SD 2.89%
Bone: Chondrosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 210

			Male	Female	
#Bone: Chondrosarcoma or Cl	hondroma	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	(0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0	0%
#Bone: Chordoma					
		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/50 (0%)	%) 0/50 (0%) 0/50 0/50 0/50 (0%)	(0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.1%	(11)	
#Bone: Osteoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	(0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	% Total 0/200 (0%) Mean 0% SD 0	
#Bone: Osteosarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 0/50 (0%)	%) 0/50 (0%) 0/50 1/50 (2%) 0/50 (0%)	(0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79%	` ,	1%
#Bone: Osteosarcoma or Oste					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 1/50 (2%)	%) 0/50 (0%) 0/50 1/50 (2%) 0/50 (0%)	(0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2% SD 1.79%	` '	1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 211

			Male		Female
*Brain: Astrocytoma Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	6) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/200 (0%)	Mean 0% SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%) 0/49 (0%		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/200 (0%)	0/50 (0%) Mean 0% SD 0%
*Brain: Ependymoma Malignant	•••••	0/50 (0%)	0/50 (0%) 1/49 (2%		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.41% SD 0.919	0/50 (0%)	0/50 (0%) Mean 0% SD 0%
*Brain: Glioma Malignant	• • • • • • • • • • • • • • • • • • • •				
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/249 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) 0/50 (0%) Total 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Brain: Granular Cell Tumor Benig					0/50 (0%)
Overall Incidence	Total	2/50 (4%) 0/50 (0%) 2/249 (0.8%)	0/50 (0%) 0/49 (0%) 0/50 (0%) Mean 0.8% SD 1.79%	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F344

: May2009

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 212

			Male				Female	
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/40 (070)		0/50 (0%)	0/50 (0%)	0/00 (0/0)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mali	gnant. NOS							
	g, 1100	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Benig	n							
g gg	-	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligr								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 213

			Male				Female	
Brain:								
Oligodendroglioma, Gli	ioma, or Astroc	-	0/50 (00/)	0/40 (00/)		0/50 (00/)		0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain:								
Osteosarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/40 (070)		0/50 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain:								
Schwannoma Malignan	nt	0/50 (00/)	0/50 (00/)	0/40 (00/)		0/50 (00/)		0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
Adenoma		4/50 (00/)	E/E0 (400()	0/50 (00/)		40/50 (000/)		E/E0 (400()
		1/50 (2%) 2/50 (4%)	5/50 (10%) 1/50 (2%)	0/50 (0%)		10/50 (20%) 8/50 (16%)	11/50 (22%)	5/50 (10%)
Overall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 3.85%	Total	34/200 (17%)	Mean 17%	SD 5.29%
		, ,				` ,		
Clitoral/Preputial Gland:								
Carcinoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0.750 (00.4)	4/50 (8%)
	<b>-</b>	0/50 (0%)	2/50 (4%)	00 0 100/	<b>-</b>	2/50 (4%)	3/50 (6%)	OD 0 4007
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%	Total	9/200 (4.5%)	Mean 4.5%	SD 3.42%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

sion. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 214

			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%) 2/50 (4%)	5/50 (10%) 3/50 (6%)	2/50 (4%)		10/50 (20%) 10/50 (20%)	14/50 (28%)	9/50 (18%)
verall Incidence	Total	13/250 (5.2%)	Mean 5.2%	SD 3.03%	Total	43/200 (21.5%)	Mean 21.5%	SD 4.43%
Clitoral/Preputial Gland: Fibrosarcoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0(50 (00())	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Esophagus: Fibrosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Esophagus: Lipoma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Eye: Amelanotic Melanoma, Benign 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% #Eye: Melanoma Malignant 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** 0/250 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%)Mean 0.4% SD 0.89% Total 0/200 (0%)Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

L

Page: 216

Report Date:04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
#Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign								
• • • • • • • • • • • • • • • • • • •		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Heart: Schwannoma Malignant			•••••	•••••		•••••	•••••	
ochwalinoma mangham		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Large: Colon/Rectum Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

i. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 217

			Male				Female	
Intestine Large: Colon/Rectun Carcinoma	1:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Large: Colon/Rectun Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
fintestine Large: Colon/Rectun Hemangioma	i:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Small: Duodenum:	•••••							
our on on o		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	00.0004	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Leiomyoma		0.50	2(72 (221)	2/52 (224)		0.50		2(52)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

i. Way2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 218

			Male				Female	
fintestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Small: Jejunum: Granular Cell Tumor Ma								
	J	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Leiomyoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
2010my Cour Coma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,				,		
Intestine Small: Site Unspe Carcinoma	ecified:							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F344

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Page: 219 Report Date:04/29/2009

Species: RATS

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

			Male		Female	
Intestine Small: Site Unsp Carcinoma or Adenom						
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	` '	0.89% Total	0/200 (0%)	SD 0%
ntestine Small: Site Unsp Granular Cell Tumor M						
	· ·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	` '	0% Total	0/200 (0%) Mean 0%	SD 0%
Intestine Small: Site Uns Leiomyoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD	0% Total	0/200 (0%) Mean 0%	SD 0%
ntestine Small: Site Unsp						
Leiomyosarcoma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% SD	0% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
Islets, Pancreatic: Adenoma						
		1/50 (2%) 3/50 (6%)	1/49 (2%) 7/50 3/50 (6%)	(14%)	2/49 (4%) 0/49 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	15/249 (6.02%)	` ,	4.89% Total	2/195 (1.03%) Mean 1.02%	SD 2.04%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: RATS

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Islets, Pancreatic: Carcinoma								
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	0/40 (00/)	0/49 (0%)
Overall Incidence	Total	0/50 (0%) 3/249 (1.2%)	1/50 (2%) Mean 1.21%	SD 1.1%	Total	0/49 (0%) 0/195 (0%)	0/48 (0%) Mean 0%	SD 0%
	1 Olai	,	Wearr 1.21/6			,		
slets, Pancreatic: Carcinoma or Adenoma	ı							
		2/50 (4%)	2/49 (4%)	7/50 (14%)		2/49 (4%)	0/40 (00/)	0/49 (0%)
Verall Incidence	Total	3/50 (6%)	4/50 (8%)	CD 4.420/	Total	0/49 (0%)	0/48 (0%)	CD 2.040/
Overall Incidence	Total	18/249 (7.23%)	Mean 7.22%	SD 4.13%	Total	2/195 (1.03%)	Mean 1.02%	SD 2.04%
Kidney: Pelvis and Transiti Carcinoma		m:	•••••			•••••		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)
		0/48 (0%)	0/50 (0%)			0/48 (0%)	0/48 (0%)	
verall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/192 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transiti Carcinoma or Adenoma	ional Epitheliu							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)
		0/48 (0%)	0/50 (0%)			0/48 (0%)	0/48 (0%)	
verall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/192 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transiti Papilloma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 1/48 (2%)	0/48 (0%)	0/49 (0%)
		U/40 (U70)	0/30 (0%)			1/40 (270)	0/48 (0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

### Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Kidney: Renal Tubule: Adenoma 0/50 (0%)0/50 (0%)(0%)0/47 (0%)0/49 (0%)(0%)(0%)(0%)0/48 0/50 0/48 0/48 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/192 (0%) Mean 0% SD 0% \*Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/47 (0%)(0%)0/48 (0%)(0%)0/48 (0%)0/48 **Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/192 (0%) Mean 0% SD 0% \*Kidney: Renal Tubule: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(0%)0/47 (0%)0/49 (0%)(0%)0/48 (0%)0/50 (0%)0/48 **Overall Incidence** SD 0% SD 0% Total 0/248 (0%) Mean 0% Total 0/192 (0%) Mean 0% \*Kidney: Renal Tubule: Hemangiosarcoma (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/48 (0%)0/50 (0%)0/48 (0%)(0%)**Overall Incidence** Mean 0% SD 0% 0/192 (0%) SD 0% Total 0/248 (0%) Total Mean 0% \*Kidney: Renal Tubule: Lipoma (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/48 (0%)0/48 (0%)**Overall Incidence** Total 0/248 (0%)Mean 0% SD 0% Total 0/192 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 222

			Male		Female
Kidney: Renal Tubule: Mesenchymal Tumor Be	nign				
·		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/47 (0%) 0/48 (0%)	0/49 (0%) 0/48 (0%)
overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/192 (0%)	Mean 0% SD 0%
Kidney: Renal Tubule: Nephroblastoma					
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/47 (0%) 0/48 (0%)	0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/192 (0%)	Mean 0% SD 0%
Kidney: Renal Tubule: Sarcoma					
		0/50 (0%) 1/48 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/47 (0%) 0/48 (0%)	1/49 (2%) 0/48 (0%)
overall Incidence	Total	1/248 (0.4%)	Mean 0.42% SD 0.93	` ,	0/48 (0%) Mean 0.51% SD 1.02%
_iver:					
Cholangioma		1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/50 (0%) 2/250 (0.8%)	1/50 (2%) Mean 0.8% SD 1.1%	0/50 (0%) 5 Total 0/200 (0%)	0/50 (0%) Mean 0% SD 0%
Liver: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%	0/50 (00/)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

## **Toxicology Data Management System**

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Adenoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)		0/50 (0%)
		0/50 (0%)	3/50 (6%)	(=70)		0/50 (0%)	2/50 (4%)	(676)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%
*Liver: Hepatocellular Carcinoma					••••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 00/
Overall incidence	Total	0/250 (0%)	wean 0%	SD 0%	lotai	0/200 (0%)	wean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatob	lastoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver:		- Waster Asternance	•••••		• • • • • • • • • • • • • • • • • • • •			
Hepatocellular Carcinoma	or Hepatoc	ellular Adenoma 1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)		0/50 (0%)
		0/50 (0%)	3/50 (6%)	1700 (270)		0/50 (0%)	2/50 (4%)	0/00 (0/0)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%
*Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocell	ular Adenoma, or						
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (40/)	0/50 (0%)
Overall Insidence	T-4-1	0/50 (0%)	3/50 (6%)	CD 0.450/	Tatal	0/50 (0%)	2/50 (4%)	CD 0.240/
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female	
*Lung: Alveolar/Bronchiolar Ade	enoma	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50	(2%)
Overall Incidence	Total	0/50 (0%) 2/250 (0.8%)	1/50 (2%) Mean 0.8%	SD 1.1%	0/50 (0%) Total 2/200 (1%)	0/50 (0%)	1.15%
*Lung: Alveolar/Bronchiolar Car	cinoma						
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%	0/50 (0%) 0/50 (0%) Total 1/200 (0.5%)	0/50 1/50 (2%) Mean 0.5% SD	(0%) 1%
*Lung: Alveolar/Bronchiolar Car Adenoma	cinoma or Alv	veolar/Bronchiolar					
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 3/250 (1.2%)	1/50 (2%) 1/50 (2%) Mean 1.2%	1/50 (2%) SD 1.1%	1/50 (2%) 0/50 (0%) Total 3/200 (1.5%)	1/50 1/50 (2%) Mean 1.5% SD	(2%) 1%
*Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	0/50 (0%) Total 0/200 (0%)	0/50 (0%) Mean 0% SD	0%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	0/50 (0%) 0/50 (0%) Total 0/200 (0%)	0/50 (0%) Mean 0% SD	,

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Lung: Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ung: Squamous Cell Carcinoma			(201)		•••••			
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 226

				M	ale						Fema	ale		
#Mammary Gland: Carcinoma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/50 2/50	(0%) (4%)	4/50	(8%)	4/50	(8%)
Overall Incidence	Total	0/250	` '	Mear			0%	Total	10/200	` ,	Mear			3.83%
Mammary Gland: Carcinoma or Adenoma														
		0/50 0/50	(0%) (0%)	1/50 0/50	(2%) (0%)	0/50	(0%)		1/50 2/50	(2%) (4%)	4/50	(8%)	6/50	(12%)
Overall Incidence	Total	1/250	` ,		0.4%		0.89%	Total	13/200	` ,		n 6.5%		4.43%
Mammary Gland: Fibroadenoma					•••••		•••••		• • • • • • • • • • • • • • • • • • • •			• • • • • • • • • • • • • • • • • • • •	•••••	•••••
		2/50 3/50	(4%) (6%)	0/50 0/50	(0%) (0%)	1/50	(2%)		29/50 24/50	(58%) (48%)	28/50	(56%)	30/50	(60%)
Overall Incidence	Total	6/250	(2.4%)	Mear	2.4%		2.61%	Total	111/200	(55.5%)	Mear	n 55.5%		5.26%
Mammary Gland: Fibroma					•••••								•••••	
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
overall Incidence	Total	0/250	` ,	Mear	` '	SD	0%	Total	0/200 (	` '	Mear	` '	SD	0%
Mammary Gland: Fibroma, Fibroadenoma or				•••••				•••••						
· ···· · · · · · · · · · · · · · · · ·		2/50 3/50	(4%) (6%)	1/50 0/50	(2%) (0%)	1/50	(2%)		30/50 24/50	(60%) (48%)	28/50	(56%)	30/50	(60%)
Overall Incidence	Total	7/250	` ,		2.8%	SD	2.28%	Total	112/200	` ,		(56%) n 56%	SD	5.66%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, o	or Adenoma						
,	ŕ	2/50 (4%) 3/50 (6%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		30/50 (60%) 25/50 (50%)	28/50 (56%)	31/50 (62%)
Overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%	Total	114/200 (57%)	Mean 57%	SD 5.29%
#Mesentery: Fibrosarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Mesentery: Hemangiosarcoma					•••••			
<b>.</b>		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Lipoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Rhabdomyosarcoma					•••••			
,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 228

			Male				Female	
Nose:								
Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/00 (0/0)		0/49 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Nose:			•••••			•••••		•••••
Chondroma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
verali incidence	i Olai	0/249 (0%)	Mean 0%	3D 0%	I Olai	0/199 (0%)	Mean 0%	3D 0%
Nose: Squamous Cell Carcino	ma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa,		vnx, Tooth, Gingiva):						
Papilloma Squamous or	r Papilloma	. (50.)	2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (	. (=0 (00)		2/22 (22/)		. (=0 (00)
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total		1/50 (2%) Mean 1.2%	SD 1.1%	Total	(/	0/50 (0%) Mean 0.5%	SD 1%
		3/250 (1.2%)				1/200 (0.5%)		
Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary							
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0%)	0/30 (0%)			0/30 (0%)	0/30 (0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

			Male	Female
#Oral Cavity (Oral Mucosa, Tor Squamous Cell Carcinoma				
Papilloma		1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 1/50 (2%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6% SD 1.67%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#Oral Mucosa: Squamous Cell Carcinoma				
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total 0/200 (0%) Mean 0% SD 0%
#Oral Mucosa: Squamous Cell Papilloma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Ovary: Cystadenoma				
Cystadenoma				0/50 (0%) 0/50 (0%)
Overall Incidence				0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Ben	ian			
Granulosa Cell Tullior Bell	igii			0/50 (0%)
Overall Incidence				Total 0/200 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant				
C. a. a. c.		0/50 (0%)	0/50 (40/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/200 (1%)	2/50 (4%) Mean 1%	SD 2%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)		0/50 (0%)
Overall leaders	Tatal	0/50 (0%)	2/50 (4%)	CD 201/
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%
*Ovary:				•••••
Granulosa-Theca Tumor Benign		1/50 (2%)		0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0.5%	SD 1%
Overall incidence	rotar	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary:				
Granulosa-Theca Tumor Malignant		0/50 (0%)		0/50 (0%)
	<del>-</del>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Tubulostromal Adenoma		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	(111)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 231 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
*Pancreas: Adenoma				
		0/49 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%) 2/50 (4%)	0/49 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2% SD 1.79%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Carcinoma				
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Carcinoma or Adenoma				
		0/49 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%) 2/50 (4%)	0/49 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2% SD 1.79%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Benign				
•		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Malignant				
		0/49 (0%) 0/50 (0%)	0/49 (0%) 1/50 (2%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4% SD 0.89%	Total 0/195 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED ps **Report Date**:04/29/2009

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			Male				Female	
Parathyroid Gland:								
Adenoma		1/45 (2%)	1/46 (2%)	0/49 (0%)		0/48 (0%)		0/49 (0%)
		1/48 (2%)	0/50 (0%)	(2,75)		0/50 (0%)	0/49 (0%)	(57.5)
verall Incidence	Total	3/238 (1.26%)	Mean 1.3%	SD 1.18%	Total	0/196 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant						•••••		
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
	ı olai	0/230 (0/0)	Wearr 070	3D 070	I Olai	0/200 (0/6)	Wearr 070	
#Peripheral Nerve: Schwannoma: Benign, N	lalignant, NOS	<b>3</b>						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Pituitary Gland: Pars Distali Adenoma		ied Site:						
		10/50 (20%)	20/50 (40%)	8/50 (16%)		24/49 (49%)	00/50 (400/)	25/50 (50%)
Normall In airlean an	Tatal	16/49 (33%)	13/50 (26%)	CD 0.040/	Tatal	29/48 (60%)	20/50 (40%)	CD 0.000/
overall Incidence	Total	67/249 (26.91%)	Mean 26.93%	SD 9.64%	Total	98/197 (49.75%)	Mean 49.85%	SD 8.36%
Pituitary Gland: Pars Distali Carcinoma						•••••		•••••
Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%) 0/48 (0%)	1/50 (2%)	0/50 (0%)
Carcinoma		0/49 (0%)	0/50 (0%)					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 233

			Male				Female					
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma												
Carolilonia of Adenoma		10/50 (20%) 16/49 (33%)	20/50 (40%) 8/ 13/50 (26%)	(50 (16%)		25/49 (51%) 29/48 (60%)	21/50 (42%)	25/50 (50%)				
Overall Incidence	Total	67/249 (26.91%)	Mean 26.93%	SD 9.64%	Total	100/197 (50.76%)	Mean 50.86%	SD 7.54%				
Pituitary Gland: Pars Distalis Ganglioneuroma						•••••						
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/ 0/50 (0%)	(50 (0%)		0/49 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/249 (0%)	` '	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%				
Pituitary Gland: Pars Interme Adenoma					•••••							
		0/50 (0%) 0/49 (0%)	( )	(50 (0%)		0/49 (0%) 0/48 (0%)	0/50 (00/)	0/50 (0%)				
Overall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/48 (0%) 0/197 (0%)	0/50 (0%) Mean 0%	SD 0%				
Pituitary Gland: Pars Interme Carcinoma					•••••	•••••						
Garomonia		0/50 (0%)	` ,	(50 (0%)		0/49 (0%)	0/50 (00/)	0/50 (0%)				
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/197 (0%)	0/50 (0%) Mean 0%	SD 0%				
Pituitary Gland: Pars Interme Carcinoma or Adenoma					•••••							
		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/ 0/50 (0%)	(50 (0%)		0/49 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/249 (0.4%)	` '	SD 0.89%	Total	0/46 (0%)	0/30 (0%) Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 234

			Male	Female
*Prostate: Adenoma		0.70		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	
*Prostate: Carcinoma or Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	
*Salivary Glands: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
#Seminal Vesicle: Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	
#Skeletal Muscle: Fibrous Histiocytoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 235

			Male				Female	
#Skeletal Muscle: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle:						•••••		
Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	- 1 1 1	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
		,				,		30 0%
Skeletal Muscle: Rhabdomyosarcoma or l	Rhabdomyom		0/50 (09/)	4/50 (20/)		0/50 /00/		0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

te: ORAL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

				Ma	ale						Fema	le		
#Skeletal Muscle: Sarcoma														
		0/50 0/50	(0%) (0%)		(0%) (0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total		(0%)	Mean		SD 0%		Total	0/200	` ,	Mean		SD	
Skin: Basal Cell Adenoma														
		1/50 1/50	(2%) (2%)		(0%) (0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	2/250	` ,		0.8%	SD 1.	1%	Total	0/200	` ,	Mean	` '	SD	0%
Overall Incidence	Total	1/50 1/50 2/250	(2%)	0/50	(0%) (0%) n 0.8%	0/50 ( SD 1.	(0%) 1%	Total	0/50 0/50 0/200	(0%) (0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD (	(0%) 0%
_	osquamous	Γumor Ben	ign, or											
Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous	1/50	(2%)		(0%)	0/50 (	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous 1 Total		(2%) (2%)	0/50	(0%) (0%) n 0.8%	0/50 ( SD 1.	` ,	Total	0/50 1/50 2/200	(2%)	0/50 Mean	(0%) 1%		(2%) 1.15%
Basal Cell Adenoma, Bas Trichoepithelioma Overall Incidence	Total	1/50 1/50 2/250	(2%) (2%) (0.8%)	0/50 Mean	(0%) n 0.8%	SD 1.	1%		1/50 2/200	(2%) (1%)	Mean	1%	SD	1.15%
Trichoepithelioma  Overall Incidence  #Skin:	Total	1/50 1/50 2/250	(2%) (2%) (0.8%)	0/50 Mean	(0%) n 0.8%	SD 1.	1%		1/50 2/200	(2%) (1%)	Mean	1%	SD	1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			ı	/lale				Female				
#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)												
1100)		0/50 (	0%) 0/50	(0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)			
		0/50	0%) 1/50	(2%)	, ,		0/50 (0%)	0/50 (0%)	, ,			
Overall Incidence	Total	1/250 (0.4	,	ın 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%			
Skin: Basal Cell Carcinoma, Tumor (benign, maligr	, Basal Cell Ader	noma, Basosqu Trichoepithelid	uamous oma									
			2%) 0/50 2%) 1/50	(0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	3/250 (1.2	•	(2%) ın 1.2%	SD 1.1%	Total	2/200 (1%)	0/50 (0%) Mean 1%	SD 1.15%			
, veran incluence	iolai	3/230 (1.2	/0) IVIE	III 1.Z/0	JD 1.170	i otal	21200 (170)	IVICALI I /0	JD 1.13/0			
#Skin: Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	oma, Adenoma,	Papilloma, Sq										
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	oma, Adenoma, nthoma, Trichoe	Papilloma, Sq pithelioma 4/50 (3/50 (	8%) 1/50 6%) 6/50	(2%) (12%)	2/50 (4%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	1/50 (2%)			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (3/50 (16/250 (6.40)	8%) 1/50 6%) 6/50 4%) Mea	(12%) In 6.4%	SD 3.85%	Total	2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (3/50 (16/250 (6.40)	8%) 1/50 6%) 6/50 4%) Mea	(12%) In 6.4%	SD 3.85%		2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (6 3/50 (6 16/250 (6.	8%) 1/50 6%) 6/50 4%) Mea 	(12%) In 6.4% (2%)	SD 3.85%		2/50 (4%) 4/200 (2%) 0/50 (0%)	Mean 2%	SD 1.63%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (i 3/50 (i 16/250 (6	8%) 1/50 6%) 6/50 4%) Mea 	(12%) un 6.4% (2%) (6%)	SD 3.85% 5/50 (10%)		2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%)	Mean 2%	SD 1.63%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar  Overall Incidence  #Skin: Fibroma  Overall Incidence	oma, Adenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (6.3/50 (6.16/25	8%) 1/50 6%) 6/50 4%) Mea 	(12%) an 6.4% (2%) (6%) an 8.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2% 1/50 (2%) Mean 1.5%	SD 1.63% 1/50 (2%) SD 1%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma	Total  Total  Total	Papilloma, Sq pithelioma 4/50 (3/50 (6.16/250	8%) 1/50 6%) 6/50 4%) Mea 	(12%) an 6.4% (2%) (6%) an 8.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2%	SD 1.63% 1/50 (2%) SD 1%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar  Overall Incidence  #Skin: Fibroma  Overall Incidence  #Skin: Fibroma  Fibroma	Total  Total  Total	Papilloma, Sq pithelioma 4/50 (i 3/50 (i 16/250 (6	8%) 1/50 6%) 6/50 4%) Mea 	(12%) in 6.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2% 1/50 (2%) Mean 1.5%	SD 1.63% 1/50 (2%) SD 1%			
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar  Overall Incidence  #Skin: Fibroma  Overall Incidence  #Skin: Fibroma  Fibroma	Total  Total  Total	Papilloma, Sq pithelioma 4/50 (i 3/50 (i 16/250 (6	8%) 1/50 6%) 6/50 4%) Mea 	(12%) an 6.4% (2%) (6%) an 8.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2% 1/50 (2%) Mean 1.5%	SD 1.63% 1/50 (2%) SD 1%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 238

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Fibrosarcoma								
Fibrosarcoma		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrosarcoma, Sarcoma, M	Myxosarcom	a, or Fibrous						
пізносуюна		0/50 (0%) 0/50 (0%)	3/50 (6%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Skin: Fibrous Histiocytoma								
FIDIOUS HISTIOCYTOHIA		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Keratoacanthoma 3/50 1/50 (4%)0/50 (0%)(0%)(2%)1/50 4/50 (8%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 11/250 (4.4%) Mean 4.4% SD 2.61% Total 0/200 (0%) Mean 0% SD 0% #Skin: Lipoma 0/50 (0%)1/50 0/50 (0%)(0%)0/50 (0%)(2%)0/50 (0%)0/50 **Overall Incidence** Total 3/250 (1.2%) SD 1.1% Total 0/200 (0%) Mean 0% SD 0% Mean 1.2% #Skin: Liposarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% #Skin: **Neural Crest Tumor** 1/50 (2%)0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** 1/250 (0.4%) SD 0.89% SD 1% Total Mean 0.4% Total 1/200 (0.5%) Mean 0.5% #Skin: **Neural Crest Tumor, Malignant** 0/50 (0%)(0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%)Mean 0.4% SD 0.89% Total 0/200 (0%)Mean 0% SD 0%

Page: 239

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

### **Toxicology Data Management System** Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 240

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibroma or Schwar	nnoma benign	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin:		valianant on NOC)						
Neurofibrosarcoma or S	cnwannoma (n	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neu malignant or NOS)	ırofibroma, or	Schwannoma (benign,						
,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)		2/50 (4%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 2/250 (0.8%)	1/50 (2%) 1/50 (2%) Mean 0.8%	SD 1.1%	Total	0/50 (0%) 0/50 (1%)	0/50 (0%) Mean 1%	SD 2%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: F344

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 241 Report Date:04/29/2009

			Male				Female	
#Skin: Schwannoma Malignant								
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinon	ma					•••••		•••••
		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Squamous Cell Carcinor Basosquamous Tumor (								
Overall Incidence	Total	0/50 (0%) 1/50 (2%) 3/250 (1.2%)	0/50 (0%) 2/50 (4%) Mean 1.2%	0/50 (0%) SD 1.79%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%
		1/50 (2%) 3/250 (1.2%) 	2/50 (4%) Mean 1.2% 	,	Total	0/50 (0%) 1/200 (0.5%) 	Mean 0.5%	,
Skin: Squamous Cell Papillom		1/50 (2%) 3/250 (1.2%)	2/50 (4%) Mean 1.2%	SD 1.79%	Total Total	0/50 (0%) 1/200 (0.5%)	` '	SD 1%
Skin: Squamous Cell Papillom Overall Incidence Skin:	n <b>a</b> Total	1/50 (2%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	2/50 (4%) Mean 1.2%  0/50 (0%) 1/50 (2%)	SD 1.79%		0/50 (0%) 1/200 (0.5%) 0/50 (0%) 1/50 (2%)	Mean 0.5%	SD 1% 0/50 (0%)
Overall Incidence  #Skin: Squamous Cell Papillom  Overall Incidence  #Skin: Squamous Cell Papillom	n <b>a</b> Total	1/50 (2%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	2/50 (4%) Mean 1.2%  0/50 (0%) 1/50 (2%)	SD 1.79%		0/50 (0%) 1/200 (0.5%) 0/50 (0%) 1/50 (2%)	Mean 0.5%	SD 1% 0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 242

Report Date:04/29/2009

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Strain: F344 Vehicle: FEED

		Male				Female						
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma												
	3/50 (6%) 2/50 (4%)	1/50 (2%) 6/50 (12%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)					
Total	14/250 (5.6%)	Mean 5.6%	SD 3.85%	Total	2/200 (1%)	Mean 1%	SD 1.15%					
							•••••					
ia, Papilloma,	or Keratoacanthoma 3/50 (6%) 1/50 (2%)	1/50 (2%) 5/50 (10%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)					
Total	12/250 (4.8%)	Mean 4.8%	SD 3.35%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)					
Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%					
	0/50 (0%) 0/50 (0%)		0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%					
				•••••								
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)					
Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%					
	Total  a, Papilloma,  Total  Total	150 (6%) 2/50 (4%) Total 14/250 (5.6%)  a, Papilloma, or Keratoacanthoma 3/50 (6%) 1/50 (2%) Total 12/250 (4.8%)  3/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%)  Total 0/250 (0%)  Total 0/250 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)	a, Papilloma, Squamous Cell nthoma  3/50 (6%) 1/50 (2%) 2/50 (4%) 6/50 (12%)  Total 14/250 (5.6%) Mean 5.6%  a, Papilloma, or Keratoacanthoma 3/50 (6%) 1/50 (2%) 1/50 (2%) 5/50 (10%)  Total 12/250 (4.8%) Mean 4.8%   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0%  Total 0/250 (0%) Mean 0%   0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%	a, Papilloma, Squamous Cell nthoma  3/50 (6%) 1/50 (2%) 2/50 (4%) 2/50 (4%) 6/50 (12%)  Total 14/250 (5.6%) Mean 5.6% SD 3.85%  a, Papilloma, or Keratoacanthoma 3/50 (6%) 1/50 (2%) 2/50 (4%) 1/50 (2%) 5/50 (10%)  Total 12/250 (4.8%) Mean 4.8% SD 3.35%   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0%  Total 0/250 (0%) Mean 0% SD 0%   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0%  0/50 (0%) 0/50 (0%) SD 0%	a, Papilloma, Squamous Cell nthoma  3/50 (6%) 1/50 (2%) 2/50 (4%) 2/50 (4%) 6/50 (12%)  Total 14/250 (5.6%) Mean 5.6% SD 3.85% Total  a, Papilloma, or Keratoacanthoma 3/50 (6%) 1/50 (2%) 2/50 (4%) 1/50 (2%) 5/50 (10%)  Total 12/250 (4.8%) Mean 4.8% SD 3.35% Total   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0% Total	a, Papilloma, Squamous Cell  nthoma  3/50 (6%) 1/50 (2%) 2/50 (4%) 1/50 (2%)  2/50 (4%) 6/50 (12%)  Total 14/250 (5.6%) Mean 5.6% SD 3.85% Total 2/200 (1%)  a, Papilloma, or Keratoacanthoma  3/50 (6%) 1/50 (2%) 2/50 (4%) 0/50 (0%)  1/50 (2%) 5/50 (10%)  Total 12/250 (4.8%) Mean 4.8% SD 3.35% Total 1/200 (0.5%)   0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 2/200 (1%)  0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 2/200 (1%)  0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%)  0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%)	a, Papilloma, Squamous Cell nthoma  3/50 (6%) 1/50 (2%) 2/50 (4%) 0/50 (12%)  Total 14/250 (5.6%) Mean 5.6% SD 3.85% Total 2/200 (1%) Mean 1%  a, Papilloma, or Keratoacanthoma 3/50 (6%) 1/50 (2%) 5/50 (10%)  Total 12/250 (4.8%) Mean 4.8% SD 3.35% Total 1/200 (0.5%) Mean 0.5%  Total 12/250 (4.8%) Mean 4.8% SD 3.35% Total 1/200 (0.5%) Mean 0.5%   0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 2/200 (1%) Mean 1%  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 2/200 (1%) Mean 1%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 2/200 (1%) Mean 1%  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 243

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant								
<b>3</b>		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00()	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/40 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Spleen: Fibrous Histiocytoma				
•		0/50 (0%) 0/50 (0%)	0/49 (0%) 1/49 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41% SD 0.91%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Hemangioma				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Hemangiosarcoma				
<b>3</b>		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4% SD 0.89%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Leiomyosarcoma				
•		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
verall Incidence	Total	1/248 (0.4%)	Mean 0.4% SD 0.89%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/198 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Strain: F344

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 245

			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma o  Overall Incidence	or Papillon Total	na Squamous 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/30 (0/8)		0/50 (0%)	0/50 (0%)	1/30 (2/8)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Lipoma					••••••			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/30 (0/6)					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 246

			Male				Female	
#Stomach, Glandular: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		46/50 (92%) 46/50 (92%)	49/50 (98%) 46/50 (92%)	42/50 (84%)				
Overall Incidence	Total	229/250 (91.6%)	Mean 91.6%	SD 4.98%				
Гhymus: Sarcoma								
		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	0/48 (0%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
,		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	1/48 (2%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/232 (0.43%)	Mean 0.42%	SD 0.93%	Total	0/192 (0%)	Mean 0%	SD 0%
Fhymus: Thymoma Malignant								
,		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	0/48 (0%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female
Thymus: Thymoma NOS						
-		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/4 0/41 (0%)	18 (0%)	0/46 (0%) 0/47 (0%)	0/49 (0%) 0/50 (0%)
verall Incidence	Total	0/232 (0%)			otal 0/192 (0%)	Mean 0% SD 0%
Гhymus: Thymoma: Benign, Maligna						
		0/48 (0%) 0/48 (0%)	0/47 (0%) 1/4 0/41 (0%)	18 (2%)	0/46 (0%) 0/47 (0%)	0/49 (0%) 0/50 (0%)
verall Incidence	Total	1/232 (0.43%)	Mean 0.42%	SD 0.93% T	otal 0/192 (0%)	Mean 0% SD 0%
Гhyroid Gland: C-Cell: Adenoma						
		5/50 (10%) 11/47 (23%)	6/50 (12%) 7/5 5/48 (10%)	50 (14%)	3/49 (6%) 10/47 (21%)	4/50 (8%) 2/47 (4%)
verall Incidence	Total	34/245 (13.88%)	` '	SD 5.51% T	otal 19/193 (9.84%)	Mean 9.91% SD 7.73%
hyroid Gland: C-Cell: Carcinoma						
		4/50 (8%) 0/47 (0%)	1/50 (2%) 1/5 1/48 (2%)	50 (2%)	1/49 (2%) 1/47 (2%)	1/50 (2%) 0/47 (0%)
verall Incidence	Total	7/245 (2.86%)	,	SD 3.03% T	otal 3/193 (1.55%)	Mean 1.54% SD 1.03%
Thyroid Gland: C-Cell: Carcinoma or Adenoma						
		9/50 (18%) 11/47 (23%)	7/50 (14%) 8/5 6/48 (13%)	50 (16%)	4/49 (8%) 11/47 (23%)	5/50 (10%) 2/47 (4%)
Overall Incidence	Total	41/245 (16.73%)	` ,	SD 4.24% T	otal 22/193 (11.4%)	Mean 11.46% SD 8.32%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Thyroid Gland: Follicular Cell: Adenoma				
		2/50 (4%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8% SD 1.79%	Total 2/193 (1.04%) Mean 1.06% SD 2.13%
*Thyroid Gland: Follicular Cell: Carcinoma				
		0/50 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0% SD 0%	Total 1/193 (0.52%) Mean 0.53% SD 1.06%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	•••••			
		2/50 (4%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8% SD 1.79%	Total 3/193 (1.55%) Mean 1.6% SD 2.04%
#Tissue NOS: Lipoma	• • • • • • • • • • • • • • • • • • • •			
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 0%
#Tissue NOS: Paraganglioma				
<b>.</b> .		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 249

			Male				Female	
Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tongue: Squamous Cell Carcinoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fTongue: Squamous Cell Carcinoma o	or Papillon	na <b>Squamous</b> 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		1/50 (2%)
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	1/50 (2%) Mean 1.2%	SD 1.1%	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%
Tongue:								
Squamous Cell Papilloma		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

III. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 250

			Male		Female
Tooth: Odontoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/200 (0%)	0/50 (0%) Mean 0% SD 0%
Jrinary Bladder: Carcinoma					
		0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0% SD 0%	Total 0/199 (0%)	0/50 (0%) Mean 0% SD 0%
Urinary Bladder: Carcinoma or Papilloma					
		0/50 (0%) 0/49 (0%)	1/49 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.41% SD 0.91%	0/49 (0%) Total 0/199 (0%)	0/50 (0%) Mean 0% SD 0%
Jrinary Bladder:					
Hemangiosarcoma		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/199 (0%)	Mean 0% SD 0%
Urinary Bladder: Leiomyosarcoma					
		0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0% SD 0%	Total 0/199 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Papilloma		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.41%	SD 0.91%	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)		0/50 (0%)
Overall Incidence					Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%
#Uterus: Carcinoma					•••••		•••••	
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Deciduoma Benign					•••••			
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

**Toxicology Data Management System**Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

or Selected Control Animal Groups

Route: ORAL

or ruminal Groups

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Report Date:04/29/2009

Strain: F344 Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male			Female	
#Uterus: Hemangiosarcoma		0/50 (0%)	0.50 (004)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Leiomyoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Polyp Stromal		10/50 (20%) 16/50 (32%)	10/50 (20%)	14/50 (28%)
Overall Incidence	Total	50/200 (25%)	Mean 25%	SD 6%
#Uterus: Sarcoma Stromal		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal (20%)(28%)(34%) 17/50 10/50 (20%)**Overall Incidence** Total 51/200 (25.5%) Mean 25.5% SD 6.81% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% #Vagina: Sarcoma (0%) (0%)0/50 0/50 (0%)(0%)**Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% #Zymbal's Gland: Adenoma (0%)(0%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F344

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

red Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male					Female			
#Zymbal's Gland: Carcinoma									
Carcinoma		0/50 (0%) 3/50 (6%)	1/50 (2%) 0/5 0/50 (0%)	0 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	` '	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
#Zymbal's Gland: Carcinoma or Adenoma									
		0/50 (0%) 3/50 (6%)	1/50 (2%) 0/5 0/50 (0%)	0 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	` ,	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied